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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,359	04/14/2006	Henry William Lupton	LRM-36141	9858

56080 7590 03/26/2010
WHYTE HIRSCHBOECK DUDEK S.C.
INTELLECTUAL PROPERTY DEPARTMENT
33 East Main Street, Suite 300
Madison, WI 53703-4655

EXAMINER

DANEGA, RENEE A

ART UNIT	PAPER NUMBER
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3736

NOTIFICATION DATE	DELIVERY MODE
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03/26/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ptomailbox@whdlaw.com
ekenrick@whdlaw.com

Office Action Summary	Application No. 10/567,359	Applicant(s) LUPTON, HENRY WILLIAM	
	Examiner Renee Danega	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-66 and 68-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-66 and 68-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 72 recites "A method for forming an elongated guide wire or the method..." It is unclear whether the claim is drawn to a method for forming an elongated wire or some other method.

Claim Rejections - 35 USC § 103

1. Claims 52-62, 64-66, 68-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Worley et al. (US 20040019359).

- 2.

Regarding claims 52-53, 66, and 68 Worley teaches an elongated guide wire for use in a surgical or other procedure for accessing a remote site in the body of a human or animal subject, the guide wire defining a longitudinally extending central axis, and extending between a distal end for accessing the remote site and a spaced apart proximal end, a curvature controllable portion being located in the guide wire towards the distal end thereof for offsetting the distal end at an angle relative to the central axis, the curvature controllable portion comprising an elongated curvature inducing first member, and an elongated curvature inducing second member coupled to each other

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adjacent their distal ends, and extending from their distal ends axially in a proximal direction, and being moveable axially relative to each other for inducing a curved bend in the curvature controllable portion, wherein a means is provided for constraining the first and second members to move parallel to each other for inducing the curved bend in the curvature controllable portion. The first and second members are disposed side by side and are slideably moveable axially relative to each other as well as the wire being in combination a catheter (Figure 1B, 6, 7) (abstract). Worley doesn't expressly teach the device to be a guidewire but says that the inner member may contain a guide wire [0070]. It would have been an obvious substitution in view of Worley to make the inner member a guide wire for navigating a body.

Regarding claims 54-56, Worley teaches the means for constraining the first and second members to move parallel to each other comprises a guide tongue (12a) (14a) extending laterally from the second member and being slideably engageable with an axially extending corresponding guide groove in the first member. Retaining means is provided for retaining the guide tongue laterally captive in a plane in which curvature is induceable in the curvature controllable portion by the transverse cross-section of the guide tongue co-operating with the transverse cross-section of the guide groove (Figure 3B).

Regarding claim 57, the guide wire comprises an elongated tubular member (14) extending from the proximal end to the distal end and the first member is formed by the

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tubular member of the guide wire. At least one of the first and second members is of resilient material for resiliently urging the distal end of the guide wire into axial alignment with the central axis of the guide wire (Figure 2A) [0014] [0016].

Regarding claim 58, Worley teaches operating means is provided at the proximal end of the guide wire for moving one of the first and second members relative to the other for inducing the curved bend in the curvature controllable portion, and a connecting means is provided for connecting the operating means the second member (Figure 3D) [0061] [0062] [0063] [0070].

Regarding claims 59-62, Worley teaches the connecting means extends through a bore defined by the tubular member forming the guide wire. The connecting means co-operates with the tubular member forming the guide wire, so that the column strength of the connecting means is sufficient for facilitating urging of the second member relative to the first member in both axial directions. The connecting means comprises an elongated connecting wire, and the operating means is formed by a portion of the connecting wire extending from the tubular member forming the guide wire, at the proximal end thereof for facilitating urging the guide wire in at least one axial direction for urging the second member in the corresponding axial direction relative to the first member [0070] (clms 34-35).

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Regarding claim 64, Worley teaches a sleeve (50) extends from the distal end of the guide wire axially in a direction towards the proximal end thereof, and the curvature controllable portion is located within the sleeve (Figure 6).

Regarding claim 65, Worley teaches at least a portion of the guide wire adjacent the distal end thereof is of a radiopaque material [0020].

Regarding claim 69, this claim states the steps of the method providing the components of apparatus of claim 1, thus the same rationale of rejection is applicable

Regarding claims 70 and 71, the first and second members are disposed side by side and are slideably moveable axially relative to each other. The means for constraining the first and second members to move parallel to each other is provided by a guide tongue extending laterally from the second member and being slideably engageable with an axially extending corresponding guide groove in the first member (Figure 3B) [0070].

Regarding claim 72, Worley teaches a method for forming an elongated guidewire or the method comprising the steps of providing a guide wire defining a longitudinally extending central axis and extending between a distal end for accessing the remote site and a spaced apart proximal end; locating a curvature controllable portion in the guide wire towards a distal end thereof for offsetting the distal end at an angle relative to the central axis, the curvature controllable portion having an elongated curvature inducing

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first member and an elongated curvature inducing second member coupled to each other adjacent their distal ends axially in a proximal direction and are moveable axially relative to each other for inducing a curved bend in the curvature controllable portion means for constraining the first and second members to move parallel to each other for inducing the curved bend in the curvature controllable portion (Figures 1B, 6, 7)(Figure 3B).

Regarding claim 73, Worley teaches the means for constraining the first and second members to move parallel with each other is provided by a guide tongue extending laterally from the second member and being slideably engageable with and axially extending corresponding guide groove in the first member (Figure 3B).

3. Claim 63 rejected under 35 U.S.C. 103(a) as being unpatentable over Worley as applied to claim 52 above, and further in view of Gardeski.

Regarding claim 63, Worley doesn't teach a bulbous tip. However, Gardeski teaches a guide wire terminating in a bulbous tip (23) (Figure 1). It would have been obvious in view of Gardeski to provide a bulbous tip on Wilson's guide wire to prevent trauma to the body while accessing with the guide wire.

Response to Arguments

Applicant's arguments filed 11/4/09 have been fully considered but they are not persuasive. Applicant argues that there is no coupling adjacent to distal ends taught by Worley. However, since the members are all telescoping in each other (21) (19) (17) as seen in 1B, the members are all coupled to each other next to or near their distal ends

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by the lumens through which each member traverses or telescopes. Furthermore, the members are coupled via the tongue and groove retainer member (3B). Additionally, Worley teaches the system can be used for controlling and tracking over a guidewire [0009] and would be an obvious substitution for inner member (20) as stated in the rejection above.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571)270-3639. The examiner can normally be reached on Monday through Thursday 8:30-5:00 eastern time.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736